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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/015,055 | 12/10/2001 | Anna P. Catania | 259/061US | 7028 |

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| EXAMINER | |
|---|---|
| TELLER, ROY R | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1654 | |

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/015,055 | CATANIA ET AL. | |
| | Examiner | Art Unit | |
| | Roy Teller | 1654 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *13-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The amendment filed 6/28/04 is acknowledged and had been entered.

Claims 1-2 have been amended and claims 13-34 have been withdrawn.

Claims 1-12 are pending.

### *Claim Rejections - 35 USC § 112*

Claims 1-12 stand rejected under 35 U.S.C. 112, first paragraph, as being enabled for a pharmaceutical composition using alpha-MSH ending in SEQ ID NO:1, KPV, but is not reasonably enabled for a pharmaceutical composition comprising a peptide 3-13 amino acids in length which have a C-terminal sequence KPV for the reasons of record..

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that support for the amendments of a peptide 3-13 amino acids in length having a C-terminal amino acid sequence KPV (SEQ ID NO:1) may be found in the specification. The instant specification demonstrates that alpha-MSH consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, and SEQ ID NO:4 may be therapeutic in the treatment of sinusitis, see, for example, page 17, example 1 and page 19, example 2.

The breadth of the claims is excessive with regard to claiming a pharmaceutical composition comprising a peptide 3-13 amino acids in length having a C-terminal sequence KPV for the treatment of sinusitis. Applicant has only provided guidance for the use of SEQ ID NO:1-4 in the treatment of sinusitis. Applicant have provided no guidance of any other

pharmaceutical composition comprising any other protein with a C-terminal KPV sequence other than those found in alpha-MSH. In absence of evidence to the contrary, it would not be expected that any and all pharmaceutical compositions comprising a C-terminal KPV sequence would be expected to treat any and all sinusitis pathologies. Furthermore, it would not be predictable to the artisan which proteins comprising a C-terminal KPV sequence would work in the present invention, nor would it be predictable to the artisan which sinusitis pathologies could be treated with these compositions.

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

Claims 1-12 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that given the limitation of the number of amino acids in the amended claims, that there are more common attributes of the members of the genus.

The Court of Appeals for the Federal Circuit has held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir.

1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

These are genus claims. Applicant is claiming a pharmaceutical composition comprising a peptide 3-13 amino acids in length having a C-terminal sequence KPV for the treatment of sinusitis. Proteins comprising a C-terminal KPV sequence other than those found in alpha-MSH would have one or more amino acid substitutions, deletions, insertions and/or additions to alpha-MSH. The instant specification and claims do not indicate what distinguishing attributes are shared by members of the genus, other than the inclusion of a C-terminal KPV sequence. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The instant specification and claims do not provide any guidance as to what changes should be made. Structural features that could not distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus other than that they must comprise KPV and treat sinusitis. The general level and skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a C-terminal KPV

sequence alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, the applicant was not in possession of the claimed genus at the time the invention was made.

***Conclusion***

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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9/9/04

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CHRISTOPHER R. TATE
PRIMARY EXAMINER